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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,164	07/24/2006	Itzhak Bentwich	050992.0200.13USPC	2388
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ROSETTA-GENOMICS			EXAMINER	
c/o PSWS			MARTINELL, JAMES	
700 W. 47TH STREET				
SUITE 1000			ART UNIT	
KANSAS CITY, MO 64112			PAPER NUMBER	
			1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,164

Applicant(s)

BENTWICH, ITZHAK

Examiner

James Martinell

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 16 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 9/29/06 & 9/29/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Inventor's Patent Application
6) ☐ Other: _____

Art Unit: 1634

The abstract of the disclosure is objected to because it should be on a single sheet. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities. The instant application does not comply with the Sequence Rules (37 CFR §§ 1.821-1.825) in that sequences appear without identifying SEQ ID NOs. Such sequences appear in at least the following locations:

- (a) page 44, lines 14, 20, 22, and 24,
- (b) page 45, lines 8, 10, 15, 16, and 16,
- (c) page 49, lines 22, 24, and 26, and
- (d) page 50, lines 1, 3, and 4
- (e) Figure 23B, and
- (f) Figure 24A.

Appropriate correction is required.

The disclosure is objected to because of the following informalities.

- (a) Figures 2A and 2B should be discussed specifically in the description.
- (b) The priority information at page 1 of the application should appear in the first sentence. See MPEP 201.11 III.

Appropriate correction is required.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

- (a) 21,
- (b) 46,
- (c) 34,
- (d) 57,
- (e) 130,

Art Unit: 1634

- (f) 132,
- (g) 146,
- (h) 147,
- (i) 148, and
- (j) 149.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague, indefinite, incomplete, misdescriptive, and inaccurate.

- (a) The recitation of "bioinformatically detectable" (claims 1-9) is vague and indefinite because the instant application does not distinguish between bioinformatically detectable and bioinformatically undetectable. In addition, there is no art-recognized clear meaning for the term.
- (b) The recitation of "novel gene" (claims 1-9) is vague, indefinite, and incomplete because the instant application does not distinguish a novel gene

from a gene that is not novel. The claim is incomplete because novelty is relative to what is known. The instant application does not provide a list of known genes and there is no clear or art-recognized complete listing of genes that were known as of the effective filing date of the instant claims.

- (c) The recitation of "partial or accurate" (claims 1-3) is vague and indefinite because the instant application does not define what is meant by the terms within the context of the claims.
- (d) The recitation of "nucleotide sequence of a binding site associated with at least one target gene" (claims 1-3) is vague and indefinite because the meaning of "associated with" is not understood within the meaning of the phrase.
- (e) The recitation of "a function of said novel gene is bioinformatically deducible" (claims 1 and 2) is vague and indefinite because the meaning of the phrase is not clear within the context of the claims.
- (f) The recitation of "bioinformatically deducible" (claims 1, 2, 4, 5, and 6) is vague and indefinite because the instant application does not distinguish between bioinformatically deducible and bioinformatically undeducible. In addition, there is no art-recognized clear meaning for the term.
- (g) The recitation of "binding site associated with said at least one target gene" (claims 7 and 8) is vague and indefinite because the meaning of "associated with" is not understood within the meaning of the phrase.
- (h) The recitation of "selective inhibition of translation of said at least one target gene" (claim 9) is misdescriptive and inaccurate because genes are not translated, but are transcribed.
- (i) The recitation of "utilizing" (claim 12) is incomplete because "utilizing" is not a positive process step.

Art Unit: 1634

- (j) The recitation of "selectively detecting expression" (claims 15 and 16) is vague and indefinite because the instant application does not distinguish selective detection from non-selective detection.
- (k) Claim 15 is vague and indefinite because it is an improper hybrid claim. Claim 15 is a method claim that depends from a product claim.
- (l) The recitation of "gene expression detector" (claim 16) is vague and indefinite because the instant application does not define the term, nor does the term have a clear art-recognized meaning.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991) the court stated, "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (emphasis in the original) (*Vas-Cath* at page 1117). The instant application does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed" (*Vas-Cath* at page 1116). In *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993), the court also held that, "An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference a potential method for isolating it; what is required is a description of the DNA itself" (*Fiers v. Sugano*, page 1606). This view was reiterated in *Fiddes v. Baird*, USPQ2d 1481 (BPAI 1993) at page 1483, "If a conception of a DNA requires a specific definition, such as by structure,

Art Unit: 1634

formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. . . . one cannot describe what one has not conceived." The court amplified this notion with respect to inventions claiming genetic material in *Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (Fed. Cir. 1997), stating at page 1406,

"In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. . . . Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The claims are drawn to "novel genes." The instant application does not provide an adequate written description for either "genes" or "novel genes." The instant application does not provide a specific definition, such as by structure, formula, chemical name, or physical properties such that one of skill in the art would consider applicant to have been in possession of the claimed of the claimed invention at the time the application was filed.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to methods for inhibiting expression of genes in cells and thus embrace gene therapy. Somia et al (Nature Review Genetics 1: 91 (2000)) reviews the status of gene therapy as of the year 2000. Somia et al relates several pitfalls and difficulties with gene therapy methods (e.g., see page 94, column 2 through page 95, column 2 and page 97, column 2 through page 98, column 2) including difficulties with immune responses and vectors. The concluding section of the article indicates the unpredictable nature of the art of gene therapy. The instant application does not describe how one of skill in the art would be able to practice any gene therapy or other gene expression inhibition methods. Thus, one of skill in the art would be compelled to perform undue experimentation in order to practice the instant claims.

Art Unit: 1634

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

OFFICIAL FAX NUMBER

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/James Martinell/
Primary Examiner
Art Unit 1634